Kinser, Robin D.

From: Rustemeier, Klaus
Sent: Monday, May 14, 2001 5:10 AM
To: Kinser, Robin D.
Cc: Holt, Klaus von
Subject: RE: project 1164

Dear Robin,
I read your paper about repeatability and reproducibility. My general impression is that it reflects very well our current thinking about this matter.
One comment:
In the definition part, you introduce as a third major validation parameter the term "verification". This term, however, can not be found in the bullet list below. Is it identical with "accuracy"?
Regards,
Klaus

----Original Message----
From: Kinser, Robin D.
Sent: Thursday, May 10, 2001 22:15
To: Rustemeier, Klaus; remote Holt, Klaus von; Roemer, Ewald; Don Leyden (E-mail)
Cc: Kinser, Robin D.
Subject: FW: project 1164

Hi--

Just a reminder that I need your comments by Monday, May 14, 9:00 a.m. EDT at the latest. This is nearly a 3 day extension from my first request! Ok, I admit that 2 of the additional days are not working days. I look forward to hearing from you.

--Robin

----Original Message----
From: Kinser, Robin D.
Sent: Thursday, May 03, 2001 7:30 PM
To: Tricker, Anthony; Rustemeier, Klaus; Roemer, Ewald; remote Holt, Klaus von; Don Leyden (E-mail)
Cc: Kinser, Robin D.
Subject: project 1164

Dear Colleagues--

Although attempts I made to find a time when we could have a meeting were not successful, all of you have contributed to my work on Project 1164 (Repeatability and Reproducibility Assessment for Analytical Methods for Human Studies). The objective of this project is to "Develop a general approach for demonstrating repeatability and reproducibility of analytical methods to be utilized in Human Studies projects by May 15, 2001." The feedback you have provided me as we evaluated Covance draft protocols for validation and our one-on-one discussions of the outcomes of my discussions with other experts have been valuable as I drafted the attached document, which I view as the outcome for this project. Please review this draft and provide me with any comments you have by noon EDT on Friday, May 11. Don't hesitate to call or write if you wish to discuss any part of this memo with me. Keep in mind that the goal here was for a general approach, and we will always have the opportunity to amend this document if it becomes unworkable.

I am interested, of course, in all of your thoughts, but I have a few particular questions.

- Do you think I should include more detail in the definitions of components part, i.e. should I be defining accuracy and precision and stability?
- Should I give example acceptance criteria?
- Have I referenced INBIFO SOPs appropriately?

Please note that I intend to attach the FDA Draft Guidance for Bioanalytical Method Validation and have not done so on this copy. You can find it at http://www.fda.gov/cder/guidance/2578dft.pdf

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Source: https://www.industrydocuments.ucsf.edu/docs/khfk0001

Thanks again for your contributions to this endeavor so far. I look forward to receiving your comments at your earliest convenience. << File: reprepplan.doc >>

Robin

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Source: https://www.industrydocuments.ucsf.edu/docs/khfk0001